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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/660,444 | 09/11/2003 | Andrzej Chanduszeko | NMT-015 | 4893 |
| 22832 7590 06/29/2007 Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950 | | | EXAMINER YABUT, DIANE D | |
| | | | ART UNIT 3734 | PAPER NUMBER |
| | | | MAIL DATE 06/29/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/660,444

Applicant(s)

CHANDUSZKO ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-42 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-42 and 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 January 2007 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 5 March 2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by **Das** (U.S. Patent No. **5,334,217**).

Claim 37: Das discloses the method of introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members (Figures 5C, 8), introducing said hexagonally shaped flexible members through a patent foramen ovale, or PFO (Figure 8), placing at least one of the hexagonally shaped flexible members on a left atrial side of a septum primum (Figure 10), and withdrawing the at least one hexagonally shaped flexible member from the left atrial side (withdrawing one of the hexagonally shaped flexible members is considered to be shown in Figure 8 as one of the members advances through the PFO).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31, 34-35, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Roue** (U.S. Patent No. **6,290,674**).

Claims 31, 34-35, and 60-63: Roue discloses a method for stabilizing a tissue for implanting an occlusion device in a patient comprising the steps of introducing into a heart of a patient a delivery member comprising at least a first flexible member, said first

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flexible member comprising a first end portion **36** and a second free end portion (distal end of **36**), introducing said second free end portion of said first flexible member through the opening of a patent foramen ovale prior to introducing a hole through a septum primum (left side of tissue **120**), contacting said second free end portion with a left atrial side of said septum primum, and contacting first end portion of said first flexible member on a right atrial side of the septum primum (see Figures 12-13), introducing a hole through said septum primum (Figure 13), withdrawing said second free end portion of said flexible member from said left atrial side, and introducing an occlusion device or suture **108** for occluding said patent foramen ovale through said hole in said septum primum and joining tissue (Figures 14-15).

Roue does not explicitly disclose the "tissue plane **120**" having a "septum primum," however Roue does disclose that the method may be used for a septal defect such as in the patent foramen ovale (col. 13, lines 32-41) and discloses an aperture **122** that would represent a patent foramen ovale and the left and right sides of **120** in Figure 13 would represent septum primum and septum secundum tissues, respectively. Roue also discloses that one of ordinary skill in the art would also have contacted the second free end portion with the left atrial side of the septum primum and the first end portion on a right atrial side of the septum primum (col. 13, lines 42-58).

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Roue** (U.S. Patent No. **6,290,674**) in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 36: Roue does not expressly disclose a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Roue in addition to a septal defect occluder in order to more effectively ensure a tight occlusion of the PFO defect.

8. Claims 38-41 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Das** (U.S. Patent No. **5,334,217**) in view of **Roue** (U.S. Patent No. **6,290,674**).

Claims 38-41 and 64: Das does not explicitly show puncturing a hole through the septum primum. However, Roue teaches puncturing a hole through the septum primum prior to introducing a septal occlusion member (see discussion of Claims 31, 34-35, and 60-63 above) in order to deliver the septal defect closure device to effectively engage and secure the tissue, and it would have been obvious to one of ordinary skill in the art to modify Das by providing a hole through the septum primum for delivering the septal defect closure device, as taught by Roue in order to effectively deliver the closure device to ensure secure engagement of the tissues.

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Das** (U.S. Patent No. **5,334,217**), as applied to Claim 37 above, in view of **Roue** (U.S. Patent No. **6,290,674**), and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 42: Neither Das nor Roue expressly disclose a tissue welding apparatus.

However, as mentioned above, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus in addition to a septal defect occluder, as taught by Sawyer, to Das and Roue in order to more efficiently occlude the PFO defect.

Response to Arguments

10. Applicant's arguments with respect to claims 31, 34-35, and 60-63 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 24 April 2007 have been fully considered but they are not persuasive.

12. The applicant argues that Das is silent as to the disks being withdrawn from the septal defect once deployed. The examiner disagrees. The disks being withdrawn from the septal defect once deployed is not recited in Claim 37. All that is required is that there is a step of withdrawing one of the hexagonally shaped flexible members, which is shown in Figure 8, as one of the members advances through the PFO, and therefore this reads on the claim.

13. The applicant also argues that Sawyer does not teach treating a patent foramen ovale. However, Sawyer teaches a tissue welding apparatus, as maintained above, and

the teaching of effectively joining tissues together with a tissue welding apparatus would have suggested a benefit to those of ordinary skill in the art, and therefore it would have been obvious to modify Roue and/or Das by using a tissue welding apparatus.

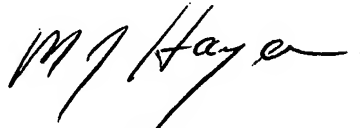
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY


MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER